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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,781	04/17/2001	Michael P. Whitman	11443/45	6776

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EXAMINER

TRAN, LOUIS B

ART UNIT PAPER NUMBER

3721

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

JH

Office Action Summary	Application No. 09/836,781	Applicant(s) WHITMAN ET AL.	
	Examiner Louis B Tran	Art Unit 3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 March 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-44 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 3/3/04
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

1. This action is in response to applicant's amendment, received on 03/03/2004.

Information Disclosure Statement

2. The information disclosure statement filed 03/03/04 fails to comply with 37 CFR 1.98(a)(3), which requires a translation of a foreign patent and concise explanation of relevance. It has been placed in the application file, but the information referred to therein has not been considered. Currently, there has been no English translation provided.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 4-6, 10, 12, 15-18, 23, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denen et al. (5,400,267).

With respect to claims 1, 12, and 23, Denen et al. teaches the use of a surgical instrument configured for complete insertion into a body for use with an electro-mechanical surgical device comprising a coupling configured to couple the surgical instrument with the electromechanical surgical device and a memory unit 30 housed inside the surgical instrument, said memory unit configured to store data representing at least one parameter, data representing a usage, a serial number relating to the surgical

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instrument, wherein a coupling 14 includes a data connector configured to connect the memory unit with the electro-mechanical surgical device.

Denen et al. does not specifically teach that a surgical instrument and memory unit can both be completely inserted into the body.

However, the invention of Denen et al. is capable of being inserted into a body completely and fulfilling the functional recitation required.

Therefore, it would have been obvious to one of ordinary skill in the art to use Denen et al. in a manner fulfilling the functional recitation.

With respect to claims 4, 15, and 26, Denen et al. teaches wherein the data is readable by a control system 36 of the electro-mechanical surgical device as in column 11, line 9 .

With respect to claim 10, Denen et al. teaches wherein the at least one parameter includes at least one of a usage data as in column 11, lines 10-25 and serial number column 3, line 23.

With respect to claim 16, Denen et al. teaches wherein the control system is configured to limit usage of the surgical instrument in accordance with the usage data as in column 11, lines 10-20.

With respect to claims 5, 17, 27, Denen et al. teaches wherein the data connector is configured to electrically and logically connect the memory unit to a control system of the electro-mechanical surgical device as described in column 7, lines 34 to 67,

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With respect to claims 6, 18, and 28, Denen et al. teaches wherein the coupling is configured to detachably attach the surgical instrument to the electro-mechanical surgical device as seen in Figure 2, for the purpose of connecting a device to a control apparatus and power supply.

5. Claims 2, 3, 7-9, 11, 13, 14, 19-22, 24, 25, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denen et al. (5,400,267) in further view of Adams et al. (6,119,913).

The device of Denen et al. discloses the invention substantially as claimed including the above discussed but does not show at least one connector configured to removably couple with at least one rotatable drive shaft of the electro mechanical surgical device.

However, Adams et al. teaches the use of at least one connector configured to removably couple with at least one rotatable drive shaft 722 of the electro mechanical surgical device as in column 10, lines 5-30 and Figure 15 (as in claim 2, 13, and 24), a first connector and a second connector, each of the connectors being configured to removably couple with a respective drive shaft 722', 724' of the electro-mechanical surgical device described in column 10, lines 10-25 (as in claims 3, 14, and 25), wherein the surgical instrument includes a surgical stapler and cutter instrument (as in claim 7, 19, and 29), wherein the surgical stapler and cutter instrument includes an anvil portion 48 and staple driver and cutter portion (as in claim 8, 20, and 30), an anvil drive shaft configured to open and close the anvil portion and a stapler drive shaft configured to

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drive the staple driver and cutter portion as in the abstract of Adams et al. (as in claim 9, 21, and 31), for the purpose of transmitting a rotation force to a surgical instrument as in column 10, lines 5-30.

Moreover, Adams also teaches at least one driven element 40 and a gear 44 arrangement configured to couple a drive shaft 22 of the electro-mechanical surgical device to the at least one driven element, the gear arrangement being configured to convert a rotation of the drive shaft to drive the at least one driven element at a torque, as inherently achieved by any gear arrangement, exemplified in Figure 2 (as in claim 11, 22 and 32)

Therefore, it would have been obvious to one having ordinary skill in the art to provide a rotatable drive shaft in order to transfer force to a surgical instrument for operation.

Although Adams does not explicitly state the rotation is high-speed rotation for high torque output, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select high speed rotation and torque over standard or slow rotation, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

6. Claim 33-41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (6,119,913) in view of Denen et al. (5,400,267).

With respect to claim 33, Adams et al. discloses the invention substantially as claimed including an electro-mechanical surgical device, a surgical instrument

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configured for complete insertion into a body for use with the electro-mechanical surgical device at least one rotatable drive shaft 22 removably attachable to the surgical instrument, a motor arrangement configured to rotate the at least one rotatable drive shaft from a proximal end thereof as described in column 6, line 35, a first gear arrangement disposed at a distal end of the rotatable drive shaft 44, and at least one element 40 driven by the gear arrangement, wherein the gear arrangement is configured to convert a rotation of the rotatable drive shaft to drive the at least one driven element at a torque as discussed in column 7, line 13.

Adams et al. does not specifically show a memory unit configured to store data representing at least one parameter relating to the surgical instrument.

However, Denen et al. teaches the common use of a memory unit 30 configured to store data for the purpose of tracking usage of limited-use devices to prevent equipment failure as in column 1, line 41.

Therefore, it would have been obvious to one having ordinary skill in the art to provide a memory unit in a surgical instrument in order to prevent usage failure.

With respect to claim 43, Adams et al. shows wherein the first gear arrangement includes at least one of a spur gear arrangement, a planetary gear arrangement, a harmonic gear arrangement, cycloidal drive arrangement, and an epicyclic gear arrangement as see in Figure 15.

With respect to claim 34, Adams et al. also shows the surgical system wherein the surgical instrument 718 is removeably attachable to the distal end of the rotatable

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drive shaft, the surgical instrument including the at least one element as best seen in Figure 15.

With respect to claim 35, Adams et al. shows wherein the first gear arrangement is disposed in the surgical instrument as in Figure 15.

With respect to claim 36, Adams et al. shows wherein the surgical instrument includes a circular surgical stapler attachment as seen in Figure 15A and 15 9.

With respect to claim 37, Adams et al. shows wherein the at least one element includes at least one of an anvil 720 of the circular surgical stapler attachment and a staple driver and cutter 38 of the circular surgical stapler attachment in the embodiments of Figure 15 and 5.

With respect to claim 38, Adams et al. shows wherein the at least one rotatable drive shaft includes a first rotatable drive shaft 722 and a second rotatable drive shaft 724 as described in column 10, line 24, wherein the at least one element includes a first element driven by the first rotatable drive shaft and a second element driven by the second rotatable drive shaft seen in Figure 15, and wherein the gear arrangement includes a first gear system configured to convert rotation of the first rotatable drive shaft to drive the first driven element at a torque and a second gear system configured to convert a rotation of the second rotatable drive shaft to drive the second driven element at a torque.

Although Adams does not explicitly state the rotation is high-speed rotation for high torque output, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select high speed rotation and torque over standard

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or slow rotation, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With respect to claims 39-41, Adams teaches wherein the motor arrangement includes a first motor configured to rotate the first rotatable drive shaft and a second motor configured to rotate the second rotatable drive shaft in column 6, lines 34-36, where items 25 and 27 may be electric motors (as in claim 39), wherein the surgical instrument is removably connectible to the distal end of the first and second rotatable drive shafts, the surgical instrument including the first and second elements as seen in Figure 15 (as in claim 40), wherein the first element includes an anvil and second element includes a staple driver and cutter(as in claim 41).

7. Claims 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (6,119,913) in view of Denen et al. (5,400,267) in further view of Hooven (5,433,721).

The modified device of Adams et al. discloses the invention substantially as claimed including a first gear arrangement including at least one of a spur gear arrangement, a planetary gear arrangement, a harmonic gear arrangement, cycloidal drive arrangement, and an epicyclic gear arrangement but does not specifically teach a second gear arrangement disposed between the motor arrangement and the at least one rotatable drive shaft, the second gear arrangement configured to convert a high torque transmitted by the motor arrangement to rotate the at least one rotatable drive shaft at the high speed.

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However, Hooven teaches the use of a second gear arrangement disposed between the motor arrangement and the at least one rotatable drive shaft, the second gear arrangement configured to convert a high torque transmitted by the motor arrangement to rotate the at least one rotatable drive shaft at the high speed (as in claim 42), a second gear arrangement including at least one of a spur gear arrangement, a planetary gear arrangement, a harmonic gear arrangement, cycloidal drive arrangement, and an epicyclic gear arrangement (as in claim 44), for the well known purpose of reducing torque where desired as in column 8, line 46 Figure 3.

Therefore, it would have been obvious to one having ordinary skill in the art to provide a second gear arrangement in order to reduce torque output for various operations, since reducing torque with secondary gearing is well known in the mechanical arts.

Conclusion

8. Applicant's remarks have been fully considered but are deemed moot in view of the new grounds of rejection.

Applicant contends that functional limitations of apparatus claims that define structural attributes of interrelated component parts of a claimed assembly are acceptable limitations and should be considered.

Examiner agrees with Applicant's assessment and contends that the functional claim language, " so that the surgical instrument and the memory unit disposed within said surgical instrument can both be completely inserted into the body", defines no structure and merely requires the ability to achieve the function. A surgeon performing

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open cavity surgery could easily use the scalpel of Denen et al. by "inserting" the instrument below the chest surface of a patient to make an incision.

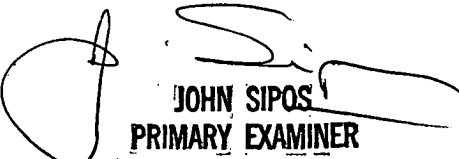
In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

For the reasons above, the grounds of rejection are deemed proper.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis B Tran whose telephone number is 703-305-0611. The examiner can normally be reached on 8AM-6PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I Rada can be reached on 703-308-2187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JOHN SIPOS
PRIMARY EXAMINER